

## USP's Commitment:

### Responding to the Opioids Crisis through Public Standards

#### Synopsis

The prescription opioid crisis is a serious<sup>1</sup> and complex<sup>2</sup> public health challenge demanding diverse solutions. Federal and state agencies, along with organizations across multiple sectors and disciplines, are working to put into place new and effective approaches to mitigate opioid misuse and abuse. The United States Pharmacopeia (USP)<sup>3</sup> commits to convene and collaborate with stakeholders to use a multipronged approach to develop results-focused solutions for the opioid crisis through up-to-date public quality standards and strategies to enable patients, families, and caregivers to understand the risks these medications pose for overdose, addiction, and diversion.

For nearly 200 years, USP's public quality standards have improved medication quality across the supply chain and healthcare continuum, including standards to assist practitioners, providers, patients, and others in safe medication storage, delivery, dispensing, and disposal. USP quality standards include methods and tests to specify the identity, strength, quality, purity, packaging, compounding, and labeling of medicines and their ingredients. Public quality standards also contribute to confidence in medicines and medicine delivery and can help promote practitioner and patient awareness of appropriate ways to prescribe, dispense, and administer medicines.

The development of USP public quality standards is built on an open, transparent, evidence-based process, offering the ability to adjust standards to adapt to new industry practices, and keep up with evolving science and technology. The process relies upon the work of independent experts in close collaboration with stakeholders and government agencies, including the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC).

USP has a well-established history of deploying its standards-setting process to address urgent public health crises. Examples include packaging standards to allow for proper administration of the anti-cancer drug Vincristine Sulfate for Injection; naming, labeling, and packaging standards for Potassium Chloride for Injection Concentrate to help prevent administration without dilution; and changes in labeling and packaging of the therapeutic class of neuromuscular blocking agent products to help prevent inadvertent mix-up.

#### USP's Commitment – Leveraging Public Standards to Contribute to Solutions to the Opioid Crisis

Working closely with stakeholders,<sup>4</sup> USP is developing an expedited approach to ensure that public quality standards for opioid drug substances and drug product monograph are up-to-date, meaning that they reflect current “state of the industry” practices and are suitable for their intended use; we are also exploring novel ways that these monographs or related approaches may be used to assist in mitigating problems including product misuse and abuse. USP is establishing an approach for consistent prescription opioid container warning labels<sup>5</sup> that can be leveraged by public health professionals, policy makers, and regulators to complement existing state policy efforts—highlighting for patients and caregivers the risks associated with opioids and supplementing and reinforcing provider and pharmacist patient education.

USP is strongly committed to developing impactful solutions for the opioids crisis and welcomes the opportunity to work collaboratively with stakeholders through *the National Academy of Medicine Action Collaborative on Countering the U.S. Opioid Epidemic* and other initiatives.

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<sup>1</sup> According to the U.S. Department of Health and Human Services, more than 2 million people have an opioid use disorder, and every year, more than 47,000 people die from opioid overdoses. U.S. Department of Health and Human Services, <https://www.hhs.gov/opioids/about-the-epidemic/index.html>.

<sup>2</sup> Complexities in responding to the opioid crisis include the addictive properties of opioids; overprescribing; patient literacy; diversion; antidote availability and appropriate use; and issues surrounding treatment.

<sup>3</sup> USP is an independent, nonprofit, scientific organization governed by a Convention comprising over 450 leading organizations and institutions in health and science from the public sector; academia; industry; healthcare practitioners; and consumer and patient communities. USP's longstanding collaboration with regulators and stakeholders has worked continuously to benefit public health through quality medicines.

<sup>4</sup> For standards-based solutions related to opioids, as with other areas, stakeholder perspectives inform USP's scientific process, driven by public health needs that become public standards. These interactions also help inform the work of a USP health literacy expert panel developing public standards and related programs. In 2017, USP sponsored an opioid discussion forum and roundtable, bringing together representatives from federal agencies, healthcare organizations, and consumer-focused groups to explore possible standards-related proposals. Concepts evaluated included consumer-directed labeling for naloxone; secure storage and proper disposal of unused opioids; prescription container labeling; and patient counseling. In March 2019, USP convened a follow-up roundtable to consider the recent development of prescription opioid container warning label proposals at the state level, in Canada, and in the United States Congress. Stakeholders explored the public health and patient safety impact of consistent container label messages, including factors to maximize label effectiveness. Participants and USP hope to apply these learnings and identify principles and approaches to encourage uniform opioid warning labels among the states.

<sup>5</sup> Patients may not be fully aware of or understand the risks posed by opioid prescriptions. Patient awareness might be enhanced by providing the patient with critical information about a medication at the point of medication use, where it may have the most utility, for example, through a prescription container label which can supplement and reinforce provider and pharmacist patient education regarding overdose, addiction, and diversion.

